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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,101	10/09/2003	Daniel F. Justin	ZIM0403	9213
7590	11/02/2009		EXAMINER	
John F. Hoffman, Esq. BAKER & DANIELS LLP Suite 800 111 East Wayne Street Fort Wayne, IN 46802			NEGRELLI, CHRISTINA L	
			ART UNIT	PAPER NUMBER
			3733	
			MAIL DATE	
			11/02/2009	DELIVERY MODE
				PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/682,101	JUSTIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	CHRISTINA NEGRELLI	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 October 2009.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 12-18 and 30-33 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 12,13,15 and 30-32 is/are rejected.  
 7) Claim(s) 14, 16-18 and 33 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/09/2009</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/07/2009 has been entered.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 12, 13, 15, and 30-32** are rejected under 35 U.S.C. 102(e) as being anticipated by Krueger et al. (US Publication No. 2006/0116768 A1).

Krueger discloses a tibial keel holder (Fig.31, ref.210) and tibial tray holder (Fig.34, ref.252) combination, the tibial keel holder being engageable with a tibial keel component (Fig.11, ref.102, 106) of a modular tibial implant, the tibial keel component having a first end and a second end, and the tibial tray holder being engageable with a

tibial tray component (Fig.11, ref.104) of a modular tibial implant, the tibial keel component and tibial tray component forming a male/female junction between them.

The combination comprises a tibial keel holder (Fig.31, ref.210) including a first handle (Fig.31, ref.234), a clamp (Fig.28, ref.218) for connecting the tibial keel holder to the tibial keel component in a reproducible known orientation, and a cover (Fig.32, ref.240), the clamp being connected to the handle and having a top surface and an opposing bottom surface, the clamp having a first position in which the clamp applies a clamping force to the tibial keel component to lock the tibial keel component to the tibial keel holder, the clamp having a second position in which the tibial keel component is moveable relative to the clamp, with the clamp in the first position in which the clamp applies a clamping force to the keel and with the second end of the tibial keel component extending from the bottom surface of the clamp with the keel component connected to the tibial keel (para.0130-0132).

The cover (fig.32, ref.240) is moveable to selectively position the cover over the first end of the tibial keel component to shield the first end of the tibial keel component from contamination while the second end of the tibial keel component extends from the bottom surface of the clamp and is engageable with a tibial bone (para.0140-0141).

Krueger further discloses a tibial tray holder (Fig.34, ref.242) including a second handle (ref.256) and an attachment mechanism (near ref.258) for connecting the tibial tray holder (ref.104) to the tibial tray component in a reproducible known orientation, the first and second handles forming a predetermined angle between them to give a visual indication of tray-to-keel rotational alignment(para.0140-0141).

Krueger further discloses wherein the clamp mechanism connects the instrument to the keel component in a reproducible known orientation such that the orientation of the handle indicates the orientation of the keel component even when the keel component is not itself visible, and wherein the attachment mechanism further comprises a first jaw (ref.218) attached to the handle and a second jaw (218) attached to the handle, the jaws being movable relative to one another to clamp the keel component (see Figs.28-29).

Krueger further discloses wherein the proper tray-to-keel alignment is indicated when the first and second handles are parallel to one another. Pusher 252 is inserted into inserter 210 and is therefore parallel. Krueger further discloses an assembly tool (Fig.32, ref.238) for moving the tibial tray component and the tibial keel component into male/female seating arrangement, the assembly tool being engageable with the tibial tray component and the tibial keel component while the tibial tray holder is holding the tibial tray (see Fig.32) (para.0135).

#### ***Allowable Subject Matter***

**Claims 14, 16-18 and 33** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments with respect to claims 12-18 in view of Lichtman (U.S. Patent No. 5,308,357) and claims 30-33 in view of Robie et al. (U.S. Patent No. 6,159,217) have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA NEGRELLI whose telephone number is (571)270-7389. The examiner can normally be reached on Mon-Fri. 7:30-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. N./  
Examiner, Art Unit 3733  
/Eduardo C. Robert/  
Supervisory Patent Examiner, Art Unit 3733